

Early oral feeding versus traditional route in patients with gastrointestinal (GI) anastomosis: a randomised controlled trial

Submission date 03/10/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 18/01/2006	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 16/10/2009	Condition category Surgery	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Study information

Scientific Title

Study objectives

A period of starvation 'nil by mouth' is a common practice after GI anastomosis. The stomach is decompressed with a nasogastric tube and intravenous fluid is administered. Then oral feeding

begins after gastric dysmotility is resolved.

The rationale of 'nil by mouth' is to prevent postoperative nausea and vomiting, in addition to providing the anastomosis some time before being stressed by food. In other words, patients are nil per os ('NPO') to prevent early complications (nausea and vomiting) and late complications of an anastomosis such as peritonitis, abscess and sepsis due to leakages of intestinal fluids into peritoneal cavity.

Contrary to the above opinion, there is evidence suggesting early feeding is beneficial.

It has been shown in animals that the 'NPO' period reduces the collagen content in anastomosed tissue and diminishes the quality of healing. Whereas feeding reverses mucosal atrophy induced by starvation and increases collagen deposition and strength of the site of anastomosis. Since a great number of GI surgeries are undertaken in malnourished patients, providing them with a chance to increase their depleted collagen storage after surgery is wise. Moreover, there are clinical investigations showing that early feeding is associated with improved wound healing and reduces septic morbidity after abdominal trauma and peritonitis. Some other studies suppose that early feeding minimizes the length of hospitalization. Additionally there are studies suggesting no significant difference in any feeding routes.

Most of the studies are surgical site specific. But this study takes all GI anastomosis into consideration, which might lead to a more general comment.

Considering the lack of data from Iran health providers on the matter, the study may also provide some help to choose more appropriate routes for our patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Different gastrointestinal pathologies lead to GI surgeries.

Interventions

Nasogastric tubes were removed immediately after surgery in both groups.

In group I (early feeding) patients, oral feeding began on the first postoperative day with liquid diet and gradually changed to normal diet as tolerated.

In group II (traditional route) feeding began with the same diet after resolution of ileus. That was defined by audible bowel sound plus no abdominal distension or vomiting.

In the case of vomiting more than twice, the nasogastric tube was reinserted in both groups.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

Decreasing the early and late complications as below:

1. Early complications (inability to tolerate oral feeding, presented with nausea and vomiting)
2. Delayed complications (due to leakage from anastomosis, such as peritonitis, abscess and sepsis, in addition to fistula and death)

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/03/2003

Eligibility

Key inclusion criteria

1. Being a candidate for GI anastomosis
2. Being a volunteer for participation

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

Key exclusion criteria

1. Peritonitis
2. Albumin level <3 mg/dl
3. Age <4 years old
4. Previous history of autoimmune disease such as rheumatoid arthritis (RA) or systemic lupus erythematosus (SLE)
5. Previous abdominal surgery
6. History of endocrine disease
7. Diabetes mellitus
8. Heart valve diseases or atherosclerosis
9. History of surgery due to abdominal trauma

Date of first enrolment

01/03/2001

Date of final enrolment

01/03/2003

Locations

Countries of recruitment

Iran

Study participating centre

General Surgery Department

Tehran

Iran

16179

Sponsor information

Organisation

Imam Hossein University Hospital (Iran)

ROR

<https://ror.org/04esb6v42>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

It is an internally funded project by the General Surgery Department of Imam Hossein University Hospital (Iran)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration